

**Information Disclosure  
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**Applicant:**

Weers et al.

**Filing Date:**

August 19, 2003

**Group:**

1616

**Other Documents**

<b>Examiner Initial</b>	<b>No.</b>	<b>Author, Title, Date, Place (e.g. Journal) of Publication</b>
	1	Advertisement for "Stop 'n Grow" manufactured by The Mentholatum Co. Ltd., East Kilbride, Scotland G74 5P3.
		Agrimi, U., et al. "Amyloid; Amyloid-Inducers, Cytokines and Heavy Metals in Scrapie and Other Human and Animal Subacute Spongiform Encephalopathies: Some Hypotheses", <i>Med. Hypotheses</i> , 40(2): 113-116 (1993).
		Akers, M.J., et al., "Glycine Crystallization During Freezing: The Effects of Salt Form, pH, and Ionic Strength", <i>Pharmaceutical Research</i> 12(10):1457-1461 (1995).
		Akoh, et al., "One-stage synthesis of raffinose fatty acid polyesters", <i>J. Food Sci.</i> , 52:1570-1576 (1987).
		Alberts, B., et al., <i>Molecular Biology of the Cell</i> , 2 <sup>nd</sup> ed., Garland Publishing, Inc., Ch. 2, page 58 (1989).
		Aldous, et al., "The Crystallization of Hydrates from Amorphous Carbohydrates", <i>Cryo-Letters</i> , 16:181-186 (1995).
		Allen, D.J., et al. "Determination of the Degree of Crystallinity in Solid-Solid Equilibria", <i>J. Pharm. Sci.</i> , 58:1190-1193 (1969).
		Allison, S.D., et al., "Mechanisms of Protection of Cationic Lipid-DNA Complexes During Lyophilization", <i>Journal of Pharmaceutical Sciences</i> 89(5): 682-691 (2000).
		Allison, S.D. and Anchordoquy, Thomas J., <i>Lyophilization of Nonviral Gene Delivery Systems, METHODS IN MOLECULAR MEDICINE, NONVIRAL VECTORS FOR GENE THERAPY</i> , Ch. 18, p 225-252 (Mark A. Findeis ed., Humana Press, 2001).
		Amidon, G.E., et al., "Powder Flow Testing in Preformulation and Formulation Development", <i>Pharm. Manuf.</i> , 2: 20-31 (1985).
		Anchordoquy, Thomas J., Physical Stabilization of DNA Based Therapeutics, 6(9): DDT 463-470 (May 2001).
		Anekwe, J., et al., "Relaxation Constants as a Predictor of Protein Stabilization", <i>Biocalorimetry: Applications of Calorimetry in the Biological Science</i> , J.E. Ladbury and B.Z. Chowdhry, editors, John Wiley & Sons, pp. 243-251 (1998).
		"Drug Absorption and Availability", Modern Pharmaceutics, 3 <sup>rd</sup> edition, G.S. Banker, et al. (eds), Marcel Dekker, Inc., pp. 145 (1996).
		Bandara, G., et al., "Interarticular Expression of Biologically Active Interleukin 1-Receptor-Antagonist Protein by Ex Vivo Gene Transfer", <i>Proc. Natl. Acad. Sci.</i> , 90:10764-10768 (November 1993).
	2	Barnett, A.H., "Exhubera Inhaled Insulin: A Review <i>Int. J. Clin. Pract.</i> 58(4): 394-401 (2004).
		Bell, J.H., et al., "Dry Powder Aerosols I: A New Powder Inhalation Device", <i>J. Pharm. Sci.</i> , 60(10): 1559-1564 (October 1971).

**Examiner:****Date Considered**

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b> Weers et al.	
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<b>Other Documents</b>			

	3	Belopol'skaya, T.V., et al., "The Effect of Water as Natural Plasticizer on Thermal Properties of Denatured DNA Studied by Calorimetry 4 VESTNIK SANKT-PETERSBURGSKOGO UNIVERSITETA SERIYA, pp. 16-22, abstract only, 2 pgs. (1999).
		Bigsbee, et al. "Solid State Liability of Insulin: Comparison of Crystalline and Amorphous Forms", <i>Pharmaceutical Research</i> 10(10): Abstract No. PDD 7418, page S-279 (1993).
		Blakeley, et al., "Dry instant blood typing for bedside use", <i>Lancet</i> , 336: 854-855 (1990).
	4	Bögelein, J., et al., "Influence of Amorphous Mannitol on Powder Properties of Spray Dried Trehalose/Dextran Mixtures", [on-line] [retrieved September 2005] Retrieved from the Internet, <URL: <a href="http://www.pharmatech.uniuerlangen.de/APV_03/bogelein.pdf">http://www.pharmatech.uniuerlangen.de/APV_03/bogelein.pdf</a> > 2 pages (2003).
		Bootsma, H.P.R., et al., "β-Cyclodextrin as an Excipient in Solid Oral Dosage Forms: In Vitro and In Vivo Evaluation of Spray-Dried Diazepam-β-Cyclodextrin Products", <i>International Journal of Pharmaceutics</i> 51:213-223 (1989).
	5	Bosquillon, C. et al., "Aerosolization Properties, Surface Composition and Physical State of Spray-Dried Protein Powders", <i>Journal of Controlled Release</i> , 99: 357-367 (2004).
	6	Branca, C., et al., "Destructuring effect of trehalose on the tetrahedral network of water: a Raman and neutron diffraction comparison", <i>Physica A</i> 304: 314-318 (2002).
		Branchu, S., et al., "The Effect of Cyclodestrins on Monomeric Protein Unfolding", <i>Biocalorimetry: Applications of Calorimetry in the Biological Sciences</i> , J.E. Ladbury and B.Z. Chowdhry (eds.), John Wiley & Sons, Ltd., 297-301 (1998).
		Branchu, S., et al., "Hydroxypropyl-β-Cyclodextrin Inhibits Spray-Drying-Induced Inactivation of β-Galactosidase", <i>Journal of Pharmaceutical Sciences</i> 88(9): 905-911 (1999).
		Brange, et al., "Chemical Stability of Insulin. I. Hydrolytic Degradation During Storage of Pharmaceutical Preparations", <i>Pharmaceutical Research</i> 9(6): 715-726 (1992).
	7	Breitenbach, J., "Melt Extrusion: From Process to Drug Delivery Technology", <i>European Journal of Pharmaceutics and Biopharmaceutics</i> 54: 107-117 (2002).
		Broadhead, J., et al., "The Effect of Process and Formulation Variable on the Properties of Spray-Drive β-Galactosidase", <i>J. Pharm. Pharmacol.</i> 46(6): 458-567 (June 1994).
		Broadhead, J., et al., "The Spray Drying of Pharmaceuticals", 18 Drug Development and Industrial Pharmacy, p. 1169-1206 (1992).
		Brown, "A Therapeutic Panorama of the Spongiform Encephalopathies", <i>Antiviral Chem. Chemother.</i> 1(2): 75-83 (1990).
		Buitink, Julia, et al., <i>High Critical Temperature above Tg May Contribute to the Stability of Biological Systems</i> , 79 BIOPHYSICAL JOURNAL, 1119-1128 (August 2000).
		Burvall, et al., "Storage of Lactose-Hydrolysed Dried Milk: Effect of Water Activity on the Protein Nutritional Value", <i>Journal of Dairy Research</i> 45: 381-389 (1978).

<b>Examiner:</b>	<b>Date Considered</b>

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(Use Several Sheets if Necessary)

**Applicant:**

Weers et al.

**Filing Date:**

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**Group:**

1616

**Other Documents**

	<u>8</u>	Byron, Peter R., et al., <i>Drug Carrier Selection – Important Physicochemical Characteristics RESPIRATORY DRUG DELIVERY</i> , 5 <sup>th</sup> Ed., Interpharm Press., 103-113 (1996).
	<u>9</u>	Byström, et al., "Microcalorimetry – A Novel Technique for Characterization of Powders", <i>Respiratory Drug Delivery IV</i> , p. 297-302 (1994).
	<u>10</u>	Carpenter, John F., et al., "Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice", <i>Pharmaceutical Res.</i> , 14(8): 969-975 (1997).
	<u>11</u>	Casselyn, M. et al., <i>Time-Resolved Scattering Investigations of Brome Mosaic Virus Microcrystals Appearance D58 ACTH CRYST.</i> 1568-1570 (2002).
	<u>12</u>	Caughey, et al., "Sulphated Polyanion Inhibition of Scrapie-Associated PrP Accumulation in Cultured Cells", <i>J. Virol.</i> , 67(2): 643-650 (1993).
	<u>13</u>	Chan, et al., "Formulation of Vaccine Adjuvant Muramylpeptides (MDP). 1. Characterization of Amorphous and Crystalline Forms of a Muramylpeptide Analogue", <i>Pharmaceutical Research</i> , 5(8): 523-527 (1988).
	<u>14</u>	Chan, Hak-Kim, et al., "Solid State Characterization of Spray-Dried Powders of Recombinant Human Deoxyribonuclease (RhDNase)", <i>Journal of Pharmaceutical Sciences</i> , 87(5): 647-654 (1998).
	<u>15</u>	Chan, Hak-Kim, et al., "Physical Stability of Salmon Calcitonin Spray-Dried Powders for Inhalation", <i>Journal of Pharmaceutical Sciences</i> , 93(3): 792-804 (2004).
	<u>16</u>	Chavan, V., et al., "Effect of Rise in Simulated Inspiratory Flow Rate and Carrier Particle Size on Powder Emptying From Dry Powder Inhalers", <i>AAPS Pharmsci 2000</i> ; 2(2) article 10 [on-line] Retrieved from the Internet <URL: <a href="http://www.pharmsci.org">http://www.pharmsci.org</a> > 7 pages (2000).
	<u>17</u>	Chavan, V., et al., "Novel System to Investigate the Effects of Inhaled Volume and Rates of Rise in Simulated Inspiratory Air Flow on Fine Particle Output From a Dry Power Inhaler", <i>AAPS Pharmsci 2000</i> ; 4(2) article 6 [on-line] Retrieved from the Internet <URL: <a href="http://www.pharmsci.org">http://www.pharmsci.org</a> > 6 pages (2002).
	<u>18</u>	Chavan, V., et al., Effect of Particle Size and Rise in Simulated Inspiratory Flow Rate on Device Emptying in a Dry Powder Inhaler SYstem", [on-line] [retrieved 01/07/2005] Retrieved from the Internet <URL: <a href="http://www.aapspharmsci.org/abstracts/AM_1999/1001.htm">http://www.aapspharmsci.org/abstracts/AM_1999/1001.htm</a> > 1 page (1999).
	<u>19</u>	Chawla, et al., "Production of Spray Dried Salbutamol Sulphate for Use in Dry Powder Aerosol Formulation", <i>International Journal of Pharmaceutics</i> , 108: 233-240 (1994).
	<u>20</u>	Chiou, et al., "Pharmaceutical Applications of Solid Dispersion Systems", <i>J. Pharm.</i> , 60(9): 1281-1302 (1971).
	<u>21</u>	Cleland, et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation and Oxidation", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 10(4): 307-377 (1993).
	<u>22</u>	Cline, D., et al., "Predicting the Quality of Powders for Inhalation", <i>Respiratory Drug Delivery VIII</i> , p. 683-685 (2002).
	<u>23</u>	Cline D., "Predicting the Quality of Powders for Inhalation from Surface Energy and Area", <i>Pharmaceutical Research</i> , 19(9): 1274-1277 (2002).

Examiner:	Date Considered

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>Other Documents</b>			

		Colaco, et al., "Extraordinary Stability of Enzymes Dried in Trehalose: Simplified Molecular Biology", <i>Bio/Technology</i> 10: 1007-1011 (1992).
		Colaco, et al., "Trehalose Stabilization of Biological Molecules", <i>Biotechnol. Internet.</i> , pp. 345, 347-350 (1992).
		Colaco, et al., "Chapter 14: Chemistry of Protein Stabilization by Trehalose", ACS Symposium Series 567, <i>Formulation and Delivery of Proteins and Peptides</i> , J.L. Cleland & R. Langer, pp. 222-240 (1994).
17		Considine, G.D., et al., <i>Van Nostrand's Scientific Encyclopedia</i> , 9 <sup>th</sup> edition, Vol. 2, Wiley-Interscience, John Wiley & Sons, Inc., Definition of Vaccines: pp. 3591-3592 (2002).
		Constantino, et al., "Moisture-Induced Aggregation of Lyophilized Insulin", <i>Pharmaceutical Research</i> , 11(1): 21-29 (1994).
		Constantino, H.R., et al., "Effect of Mannitol Crystallization on the Stability and Aerosol Performance of a Spray-Dried Pharmaceutical Protein, Recombinant Humanized Anti-IgE Monoclonal Antibody", <i>Journal of Pharmaceutical Sciences</i> , 87(11): 1406-1411 (1998).
		Craig, I.D., et al., "Maillard Reaction Kinetics in Model Preservation Systems in the Vicinity of the Glass Transition: Experiment and Theory", <i>J. Agric. Food Chem.</i> 49(10): 4706-4712 (2001).
		Crommelin, et al., "Liposomes" Chapter 3, <i>Colloidal Drug Delivery Systems</i> , J. Kreuter, editor: 73-190 (1994).
		Crowe, et al., "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules", <i>Cryobiol.</i> 27: 219-231 (1990).
		Crowe, et al., "Interactions of Sugars with Membranes", <i>Biochimica et Biophysica Acta</i> , 947: 367-384 (1988).
		Crowe, John H., et al., "The Role of Vitrification in Anhydrobiosis", <i>Annu. Rev. Physiol.</i> , 60: 73-103 (1998).
		Crowe, Lois M., et al., "Is Trehalose Special for Preserving Dry Biomaterials?", <i>Biophysical Journal</i> , 71: 2087-2093 (1996).
18		D'Cruz, N. "Relationship Between Protein Thermal Stability and Glass Transition in Gelatin Polyol and Gelatin-Water Mixtures", PROCEEDINGS OF 2004 MEETING IFT, July 12-16, 2004, Las Vegas, NV, Session 17E, Food Chemistry: Proteins, [on-line] [retrieved 11/08/04] Retrieved from the Internet <URL: <a href="http://ift.confex.com/ift/2004/techprogram/paper_23066.htm">http://ift.confex.com/ift/2004/techprogram/paper_23066.htm</a> > 17E-4 (2004).
		D'Hondt, "Possible Approaches to Develop Vaccines Against Hepatitis A", <i>Vaccine</i> 10 (Supplement 1): S48-S52 (1992).
		Daemen, et al., "The Destruction of Enzymes and Bacteria During the Spray-Drying of Milk and Whey, 2. The Effect of the Drying Conditions", <i>Neth. Milk Dairy J.</i> , 36: 211-229 (1982).

<b>Examiner:</b>	<b>Date Considered</b>

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Applicant:

Weers et al.

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**Other Documents**

	<del>Dalby, R.N., et al., "Droplets Drying and Electrostatic Collection a Novel Alternative to Conventional Commimution Techniques", <i>Journal of Biopharmaceutical Sciences</i> 3 (1/2): 091-099 (1992).</del>
19	<del>Dalby, R.N., et al., "Inhalation Therapy: Technological Milestones in Asthma Treatment", <i>Advanced Drug Delivery</i>, 55: 779-791 (2003).</del>
	<del>Dalby, et al., "Relationship Between Particles Morphology and Drug Release Properties After Hydration of Aerosols Properties Containing Liposome Forming Ingredients", <i>Pharmaceutical Research</i>, 5(10): S-94, Abstract PD 888 (1988).</del>
	<del>Darrington, et al., "Evidence for a Common Intermediate in Insulin Deamidation and Covalent Dimer Formation: Effects of pH and Aniline Trapping in Dilute Acidic Solutions", <i>Journal of Pharmaceutical Sciences</i>, 84(3): 275-282 (1995).</del>
	<del>DeCarlo, S., et al., "Unexpected Property of Trehakose as Observed by Cyro-Electron Microscopy", <i>Journal of Microscopy</i>, 196(1): 40-45 (1995).</del>
	<del>DeYoung, "The AeroDose Multidose Inhaler Device Design and Delivery Characteristics", <i>Respiratory Drug Delivery VI</i>, p. 91 (1998).</del>
	<del>Dose, et al., "Survival in Extreme Dryness and DNA-Single-Strand Breaks", <i>Advances in Space Research</i>, 12(4)221-229 (1992).</del>
20	<del>During, M.J., et al., "Long-Term Behavioral Recovery in Parkinsonian Rats by an HSV Vector Expressing Tyrosine Hydrosylase", <i>Science</i>, 266(5189): 856-857 (November 1994).</del>
	<del>Edwards, A.D., et al., "Crystallization of Pure Anhydrous Polymorphs of Carbamazepine by Solution Enhanced Dispersion with Supercritical Fluids (SEDS™)", <i>Journal of Pharmaceutical Sciences</i>, 90(8): 1115-1124 (2001).</del>
	<del>Edwards, et al., "Large Porous Particles for Pulmonary Drug Delivery", <i>Science</i>, Vol. 276, pp. 1868-1871 (June 1997).</del>
	<del>Eleutherio, et al., "Role of the Trehalose Carrier in Dehydration Resistance of <i>Saccharomyces Cerevisiae</i>", <i>Biochimica et Biophysica Acta</i>, 1156: 263-266 (1993).</del>
21	<del>Elkordy, et al., Integrity of Crystalline Lysozyme Exceeds that of a Spray-Dried Form", <i>International Journal of Pharmaceutics</i>, 247: 79-90 (2002).</del>
	<del>Fahy, et al., "Vitrification as an Approach to Cryopreservation", <i>Cryobiology</i>, 21: 407-426 (1984).</del>
22	<del>Fakes, M., et al., "Moisture Sorption Behavior of Selected Bulking Agents Used in Lyophilized Products", <i>PDA J. Pharm. Sci. Technol.</i> 54(2) 144-149, Abstract only [online] [retrieved 09/25/05] Retrieved from the Internet &lt;URL: http://www.ncbi.nlm.nih.gov.&gt; (2002).</del>
	<del>Finar, I.L., "§14. Trehalose, m.p. 203°C", under "Carbohydrate" <i>Organic Chemistry</i>, Vol. 2, Stereochemistry and the Chemistry of Natural Products, 5<sup>th</sup> edition, Longman, page. 323 (1996).</del>
	<del>Forbes, R.T., et al., "Water Vapor Sorption Studies on the Physical Stability of a Series of Spray-Dried Protein/Sugar Powders for Inhalation", <i>Journal of Pharmaceutical Sciences</i>, 87(11): 1316-1321 (1998).</del>

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		<b>Filing Date:</b>	<b>Group:</b>
		August 19, 2003	1616
<b>Other Documents</b>			

		Franks, "Freeze Drying: From Empiricism to Predictability", <i>Cryo-Letters</i> , 11: 93-110 (1990).
		Franks, "Materials Science and the Production of Shelf-Stable Biologicals", <i>Pharmaceutical Technological International</i> , 24: 24-34 (October 1991).
		Franks, "Separation, Improved Freeze-Drying, an Analysis of the Basic Scientific Principles", <i>Process Biochemistry</i> , 24(1): iii-vii (1989).
		Franks, "Accelerated Stability Testing of Bioproducts: AtTRACTIONS and Pitfalls", <i>TIBTECH</i> , 12: 114-117 (1994).
23		Fukuoka, et al., "Glassy State of Pharmaceuticals. V. Relaxation During Cooling and Heating of Glass by Differential Scanning Calorimetry", <i>Chem. Pharm. Bull</i> 39(8): 2087-2090 (August 2001).
24		"Chapter 89—Oral Solid Dosage Forms, "In Remington's Pharmaceutical Sciences, 18 <sup>th</sup> Edition, Mack Publishing Co., Gennaro, A.R., pp. 1646-1647.
25		Gonda, et al., "Characterization of Hygroscopic Inhalation Aerosols", In: Particle Size Analysis, (Eds. N.G. Stanley-Wood and T. Allen, Wiley Heyden Ltd., NY), pp. 31-43 (1981).
		Green, et al., "The Protein-Glass Analogy: Some Insights from Homopeptide Comparisons", <i>J. Phys. Chem.</i> , 98: 13780-13790 (April 1994).
		Green, et al., "Phase Relations and Vitrification in Saccharide-Water Solutions and the Trehalose Anomaly", <i>J. Phys. Chem.</i> , 93: 2880-2882 (1989).
26		Gupta, A., et al., "Single Virus Particle Mass Detection Using Microresonators with Nanoscale Thickness", <i>Applied Physics Letters</i> , 84(11): 1976-1978 (2004).
		Hahn, et al., "Solid Surfactant Solutions of Active Ingredients in Sugar Esters", <i>Pharmaceutical Research</i> , 6: 958-959 (1989).
		Hancock, et al., "Molecular Mobility of Amorphous Pharmaceutical Solids Below Their Glass Transition Temperatures", <i>Pharmaceutical Research</i> , 12(6): 799-806 (1995).
		Hancock, B.C., et al., "The Effect of Temperature on Water Vapor Sorption by Some Amorphous Pharmaceutical Sugars", <i>Pharmaceutical Development and Technology</i> , 4(1): 125-131 (1999).
27		Hancock, et al., "A Pragmatic Test of Simple Calorimetric Method for Determining the Fragility of some Amorphous Pharmaceutical Materials", <i>Pharm. Res.</i> , 15(5): 762-767 (1998).
		Hanes, et al., "Porous Dry-Powder PLGA Microspheres coated with Lung Surfactant for Systematic Insulin Delivery via the Lung", <i>Proc. Int'l. Symp. Control Rel. Bioactive Matter</i> , 24: 57-58 (1997).
		Harwood, C.F., "Compaction Effect on Flow Property Indexes for Powders", <i>J. Pharm. Sci.</i> , 60:161-163 (1971).
		Hatley, R.H.M., et al., "Stabilization of Labile Materials by Amorphous Carbohydrates Glass Fragility and the Physicochemical Properties that make Trehalose a Superior Excipient", <i>Pharmaceutical Research</i> , 13(9 Suppl.) PDD 7165: S274 (1996).
28		"Pfizer and Inhale Therapeutic Systems Enter Pulmonary Insulin Collaboration for Dry Powder Aerosol Delivery", <i>Health News Daily</i> , Vol. 7, No. 13, pp. 4-5 (January 1995).

Examiner:	Date Considered

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**Information Disclosure  
Statement By Applicant**
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(Use Several Sheets if Necessary)

**Other Documents**

	Heitefuss, R., et al., "The Stabilization of Extracts of Cabbage Leaf Proteins by Polyhydroxy Compounds for Electrophoretic and Immunological Studies", <i>Archives of Biochemistry and Biophysics</i> , 85: 200-208 (1959).
	Heller, Martin C., et al., "Protein Formulation and Lyophilization Cycle Design: Prevention of Damage Due to Freeze-Concentration Induced Phase Separation 63 BIOTECHNOLOGY & BIOENGINEERING", 166-174 (1999).
	Herrington, T.M., et al., "Physico-Chemical Studies on Sugar Glasses. I. Rates of Crystallization", <i>Journal of Food Technology</i> , 19: 409-425 (1984).
	Hickey, A. J. et al., "Behavoir of Hygroscopic Pharmaceutical Aerosols and the Influence of Hydrophobic Additives," <i>Pharmaceutical Research</i> 10(1):1-7 (1993).
	Hickey, A. J. et al., "Methods of Aerosol Particle Size Charaterization," <i>Pharmaceutical Inhalation Aerosol Technology</i> 8:219-253 (1992).
	Hoener, Betty-Ann et al., "Factors Influencing Drug Absorption and Availability" <i>Modern Pharmaceutics</i> , Gilber S. Bunker et al., eds., Marcel Dekker Inc., Chapter 4, pp. 121-153 (1996).
29	Ibrahim, A. L. et al., "Sprah Vaccination With an Improved F Newcastle Disease Vaccine. A Comparison of Efficacy With the B1 and La Sota Vaccines," <i>Br. Vet. J.</i> 139:213-219 (1983).
	Igaki, N. et al., "The Inhibition of the Maillard Reaction by L Lysine In-Vitro," <i>J. Jpn. Diabetes Soc.</i> 34(5):403-407 (1991) including English abstract.
30	Iglesias et al., "Adsorption Isotherm of Amorphous Trehalos", <i>J. Sci. food Agric.</i> 75:183-186 (1997).
	Jameel, F. et al., "Freeze Drying Properties of Some Oligonucleotides", <i>Pharmaceutical Development and Technology</i> 6(2):151-157 (2001).
	Jovanovic-Peterson, L. et al., "Jet-injected insulin is associated with decreased antibody production and postprandial glucose variability when compared with needle injected insulin in gestational diabetic women," <i>Diabetes Care</i> 16(11):1479-1484 (November 1993).
	Kachura, "Method of Drying Lactic Acid Bacteria," <i>Vinedelie I Vinogradarstvo SSSR</i> 2:49-50, English Abstract only, one page (1985).
	Kanna, K. et al., "Denaturation of Fish Muscle Protein by Dehydration" <i>Bull. Tokai Reg. Fish. Res. Lab.</i> 77:70-76 English abstract (1974).
	Karmas, R. et al., "Effect of Glass Transition on Rates of Nonenzymatic Browning in Food Systems," <i>J. Agric. Food Chem.</i> 40:873-879 (1992).
	Khan, R. "Chemistry And New Uses Of Sucrose: How Important?" <i>Pure &amp; Appl. Chem.</i> 56(7):833-844 (1984).
	Khan, R. "Cyclic Acetals Of 4,1',6'-Tricholoro-4,1',6'-Trideoxy-Galacto-Sucrose And Their Conversion Into Methyl Ether Derivatives," <i>Carb. Res.</i> 198:275-283 (1990).
	Klein, T. M. et al., "High Velocity Microprojectiles For Delivering Nucleic Acids Into Living Cells," <i>Nature</i> 327:70-73 (1987).
	Labuza et al., "Glass Transition Temperatures of Food Systems", [on-line] [retrieved 09/2005] Retrieved from the Internet <URL: <a href="http://faculty.che.umn.edu/fscn/Ted_Labuza/PDF%20files/Isotherm%20Folder/Tg%20compilation.pdf">http://faculty.che.umn.edu/fscn/Ted_Labuza/PDF files/Isotherm Folder/Tg%20compilation.pdf</a> > pp. 1-31 (January 1992).

**Examiner:****Date Considered**

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>	<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
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	<b>Filing Date:</b> August 19, 2003	<b>Group:</b> 1616

**Other Documents**

		Labrude, P. et al., "Protective Effect of Sucrose on Spray Drying of Oxyhemoglobin", <i>Journal of Pharmaceutical Sciences</i> . 78(3):223-229 (1989).
		Lai, M. C. et al., "Solid-State Chemical Stability of Proteins and Peptides", <i>Journal of Pharmaceutical Sciences</i> 88(5):489-500 (1999).
		Laube, B. L. et al., "Targeting Aerosol Deposition in Patients With Cystic Fibrosis, Effects of Alterations in Particle Size and Inspiratory Flow Rate", <i>Chest</i> 118(4): 1069-1076 (2000).
		Leidl, F., et al., "New Aspects of the Maillard Reaction in Foods and in the Human Body," <i>Ang. Chem. Int. Ed. Engl.</i> 29:565-594 (June 1990).
		Lee, C. K. <i>Developments in Food Carbohydrate</i> - 2nd edition Applied Science Publishers, London, Table of Contents, 4 pages (1980).
31		Lee, G., "Spray Drying of Proteins," Chapter 6, <i>Rational Design of Stable Protein Formulations, Theory and Practice</i> , J. F. Carpenter & M. Manning, pp. 135-158 (2002).
		Lehninger, Albert L. <i>The Molecular Basis of Cell Structure and Function BIOCHEMISTRY</i> , Chapter 31, 859-890 (Worth Publishers Inc., 2nd edition, 1975).
		Leslie, S. B. et al., "Trehalose and sucrose protect both membranes and proteins in intact bacteria during drying", <i>Appl. Env. Microbiol.</i> 61(10): 3592-3597 (1995).
		Leuner, C. et al., "Improving Drug Solubility for Oral Delivery Using Solid Dispersions", <i>European Journal of Pharmaceutics and Biopharmaceutics</i> 50:47-60 (2000).
		Levine et al., "Another View of Trehalose for Drying and Stabilizing Biological Materials," <i>Biopharm</i> 5:36-40 (1992).
		Li, Z. et al., "Realistic In Vitro Assessment of Dry Powder Inhalers", <i>Respiratory Drug Delivery VIII</i> , pp. 687-689 (2002).
		Lin, S.-Y. et al., "Solid Particles of Drug- $\beta$ -Cyclodextrin Inclusion Complexes Directly Prepared by a Spray-Drying Technique", <i>International Journal of Pharmaceutics</i> , 56:249-259 (1989).
32		Liu, Jinsong et al., "Dynamics of Pharmaceutical Amorphous Solids: The Study of Enthalpy Relaxation by Isothermal Microcalorimetry", <i>Journal of Pharmaceutical Sciences</i> 91(8):1853-1862 (2002).
33		Louey, M. D. et al., "Controlled Release Products for Respiratory Delivery", APR, 7(4):82-87 [on-line] [retrieved 09/20051 Retrieved from the Internet < URL: <a href="http://www.americanpharmaceuticalreview.com/article.aspx?article=77">http://www.americanpharmaceuticalreview.com/article.aspx?article=77</a> > 11 pages (2004).
		Louis, P. et al., "Survival Of Escherichia Coli During Drying And Storage In The Presence of Compatible Solutes" <i>Appl. Microbiol. Biotechnol.</i> 41:684-688 (1994).
		Lueckel, B. et al., "Effects of Formulation and Process Variables on the Aggregation of Freeze-Dried Interleukin-6 (IL-6) After Lyophilization and on Storage", <i>Pharmaceutical Development and Technology</i> 3(3):337-346 (1998).
		Masinde, Lwandiko E., et al., "Aerosolized Aqueous Suspension of Poly(L-lactic Acid) Microspheres", <i>International Journal of Pharmaceutics</i> , pp. 123-131 (1993).
		MacKenzie, "Collapse During Freeze Drying-Qualitative and Quantitative Aspects." <i>Freeze Drying and Advanced Food Technology</i> , edited by Goldblith, Rey and Rothmayr: 277-307 (1975).

Examiner:	Date Considered

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(Use Several Sheets if Necessary)

**Applicant:**

Weers et al.

**Filing Date:**

August 19, 2003

**Group:**

1616

**Other Documents**

	Makower, B. et al., "Equilibrium Moisture Content and Crystallization of Amorphous SUCROSE and Glucose," <i>Agric. And Food Chem.</i> 4(1):72-77 (1956).
	Martin, A. et al., States of Matter and Phase Equilibria PHYSICAL PHARMACY, PHYSICAL CHEMICAL PRINCIPLES IN THE PHARMACEUTICAL SCIENCES, 3rd. ed., Chapter 4, 62-92 (1983).
34	Masters, K. SPRAY DRYING HANDBOOK, England; Longman Scientific & Technical, 5th ed., pp. 640-642 (1991).
35	Masters, K. SPRAY DRYING HANDBOOK, England; Longman Scientific & Technical and John Wiley & Sons, Inc., 5th ed., pp. 309-352 (1991).
36	Masters, K SPRAY DRYING HANDBOOK, 5th ed., Chapters 13 and 15, pp. 491-537 and 587-642 (1991).
	Matsuda, Y. et al., "Amorphism and Physicochemical Stability of Spray Dried Frusemide," <i>J. Pharm. Pharmacol.</i> 44:627-633, received November 7, 1991 (1992).
	Mattern et al., "Formulation of Proteins in Vacuum-Dried Glasses. II. Process and Storage Stability in Sugar-Free Amino Acid Systems", <i>Pharmaceutical Development &amp; Technology</i> 4(2):199-208 (1999).
	Miller, D. P. et al., "Stabilization of Lactate Dehydrogenase Following Freeze Thawing and Vacuum-Drying in the Presence of Trehalose and Borate", <i>Pharmaceutical Research</i> 15(8):1215-1221(1998).
37	Molina, M. C. et al., "The Stability of Lyophilized Lipid/DNA Complexes During Prolonged Storage," <i>J. Pharm. Sci.</i> 93(9):2259-2273, abstract only, one page, [on-line] [retrieved 09/2005] Retrieved from the Internet <URL: <a href="http://www.ncbi.nlm.nih.gov">http://www.ncbi.nlm.nih.gov</a> >, (2004).
	Monnier et al., <i>Mechanisms of Protection Against Damage Mediated by the Maillard Reaction in Aging Gerontology</i> 37:152-165 (1991).
	Mouradian, R. et al., "Degradation of Functional Integrity During Long-Term Storage of a Freeze-Dried Biological Membrane", <i>Cryobiology</i> 22: 119-127 (1985).
	Moynihan et al., "Dependence of the Glass Transition Temperature on Heating and Cooling Rate", <i>J. Physical. Chem.</i> 78(26): 2673-2677 (1974).
	Muller, et al., "On the Influence of Molecular Forces on the Deformation of an Elastic Sphere and It's Sticking to a Rigid Plane", <i>J. Colloid Interface Sci.</i> , 77: 91 (1080).
	Mumenthaler, M. et al., "Feasibility Study on Spray-Drying Protein Pharmaceuticals: Recombinant Human Growth Hormone and Tissue-Type Plasminogen Activator," <i>Clinical Research</i> 11(1): 12-20 (1994).
	Murphy, B. R. et al., "Chapter 19: Immunization Against Viruses", in <i>Fields of Virology</i> , 2nd Edition, Volume 1, Raven Press, pp. 469-502 (1990).
	Murphy, Brian R. et al., <i>Fields Virology</i> , Volume 1, Chapter 16, <i>Immunization Against Virus Disease</i> , 467, at page 468, first full paragraph, first column, lines 26-33 (Bernard N. Fields et al. eds., Lippincott-Raven Publishers, 3rd ed. 1996).
38	Mutterlein, et al., "New Technology for Generating Inhalation Aerosols—Preliminary Results with the Piezoelectrical Pocket-Inhaler", <i>J. Aerosol Med.</i> , 1: 231 (1988).
39	Nabel, G. J. et al., "Direct Gene Transfer With DNA-Liposome Complexes in Melanoma," <i>Proc. Natl. Acad. Sci.</i> 90:11307-11311.

**Examiner:****Date Considered**

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
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<b>Other Documents</b>			

		Nabel, G. J. et al., "Immunotherapy of Malignancy by In Vivo Gene Transfer Into Tumors," <i>Hum. Gene. Ther.</i> 3(4): 3 99-4 10 (August 1992) Abstract only [on-line] [retrieved 112/21/04] Retrieved from the Internet < URL: <a href="http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&amp;db=pubmed&amp;dopt=Abstr">http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&amp;db=pubmed&amp;dopt=Abstr</a> >
		Naini, V. et al., "Particles for Inhalation Produced by Spray Drying and Electrostatic Precipitation of Different Protein-Sugar Solutions", <i>Respiratory Drug Delivery V</i> , pp. 382-384 (1996)
		Naini, V. et al., "Physicochemical Stability of Crystalline Sugars and Their Spray-Dried Forms: Dependence Upon Relative Humidity and Suitability for Use in Powder Inhalers", <i>Drug Development and Industrial Pharmacy</i> 24(10):895-909 (1998).
40		Natarajan, P., Crystallization Conditions for VIPER Entries [on-line] [retrieved 11/04/04] Retrieved from the Internet <URL: <a href="http://www.xtal.tsinghua.edu.cn/research/groups/web/material/Virus%20Crystallization%20Page.htm">http://www.xtal.tsinghua.edu.cn/research/groups/web/material/Virus%20Crystallization%20Page.htm</a> > 5 pages (last updated Jan. 3, 2002).
		Niven, R. W., "Delivery of Biotherapeutics by Inhalation Aerosol," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 12(2&3):151-231 (1995).
		Niven, R. W., "Delivery of Biotherapeutics by Inhalation Aerosols," <i>Pharmaceutical Technology</i> 72-75, 80 (July 1993).
		Norberg, J. et al., "Glass Transition in DNA From Molecular Dynamics Simulation", <i>Proc. Natl. Acad. Sci. USA</i> 93:10173-10176 (1996)
		Notter, R.H., "Physical Chemistry and Physiological Activity of Pulmonary Surfactants", In: <i>Surfactant Replacement Therapy</i> (Eds. Shapiro and Notter, Alan R. Liss, Inc., New York), Chapter 2, pp. 19-71 (1989).
41		Odegard, P. S. et al., "Inhaled Insulin: Exubera", <i>The Annals of Pharmacotherapy</i> 39:843-853 (2005).
42		Ohtake, S. et al., "Effect of pH, Counter Ion and Phosphate Concentration on the Glass Transition Temperature of Freeze-Dried Sugar-Phosphate Mixtures", <i>Pharmaceutica Research</i> 21(9):1615-1621(2004).
43		Okamoto, H. et al., "Dry Powders for Pulmonary Delivery of Peptides and Proteins", <i>Kona</i> 20:71-83 (2002).
		Oksanen et al., "The Relationship between the Glass Transition Temperature and Water Vapor Absorption by Poly(Vinylpyrrolidone)," <i>Pharmaceutical Research</i> 7(6): 654-657 and errata on page 974(1990).
		Okumura, K. et al., "Intratracheal Delivery of Calcitonin Dry Powder in Rats and Human Volunteers," <i>S.T.P. Pharmaceutical Sciences</i> 4(1)-5 pages (January, February 1994).
		Onodera et al., "Glass Transition of Dehydrated Amorphous Solid", <i>Bull. Chem. Soc. Japan</i> 41(9):222 (1968).
		Owens, D. R. et al., "Alternative Routes of Insulin Delivery," <i>Diabetic Medicine</i> 20:886-898 (2003).
		Palmer, K.J., et al., "X-Ray Diffractometer and Microscopic Investigation of Crystallization of Amorphous Sucrose", <i>Agricultural and Food Chemistry</i> 4(1): 77-81 (January 1956).
		Parks, "Studies on Glass. II The Transition Between the Glassy and Liquid States in the Case of Glucose", <i>Journal of Physical Chemistry</i> 1366-1379 (1928).

<b>Examiner:</b>	<b>Date Considered</b>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
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<b>Other Documents</b>			

		Patel, M. M. et al., "Degradation Kinetics of High Molecular Weight Poly(L Lactide) Microspheres and Release Mechanism of Lipid: DNA Complexes", <i>Journal of Pharmaceutical Sciences</i> , 93(10): 2573-2584 (2004).
		Pearlman et al., "Formulation Strategies for Recombinant Proteins: Human Growth Hormone and Tissue Plasminogen Activator", <i>Therapeutic Peptides and Proteins, Formulation, Delivery and Targeting</i> , Cold Spring Harbour, New York, pp. 23-30 (1989).
		Pekarek et al., "Double-walled polymer microspheres for controlled drug release," <i>Nature</i> 367:258-260 (1994).
		Phillips, E. et al., "Size Reduction of Peptides and Proteins by Jet-Milling", <i>Respiratory Drug Delivery VI</i> , pp. 161-167 (1998).
		Pikal, M. J., "Freeze-Drying of Proteins Part II: Formulation Selections," <i>Biopharm</i> 3(8):26-30 (October 1990).
		Pikal, M. J. et al., "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form", <i>Pharmaceutical Research</i> 14(10):1379-1387 (1997).
		Pikal et al., "Thermal Decomposition of Amorphous $\beta$ -Lactam Antibacterials", <i>Journal of Pharmaceutical Science</i> 66(9): 1312-1316 (September 1977).
		Pikal, M. J. et al., Errata of "The Stability of Insulin in Crystalline and Amorphous Solids: Observation of Greater Stability for the Amorphous Form," <i>Pharmaceutical Research</i> 15(2):362-363 (1998).
		Pine, S. H. et al., "15-3 Oligosaccharides and Polysaccharides," <i>Organic Chemistry</i> , 4a' edition. McGraw-Hill International Book Company, page 763 (1980).
		Pisecky, J., "2. Evaporation and Membrane Filtration", <i>Handbook of Milk Powder Manufacture</i> , Niro A/S, Denmark, page 3 (1997).
		Pochiari, M. et al., "Amphotericin B: A Novel Class of Antiscrapie Drugs," <i>J Infect. Dis.</i> 160(5):795-802 (November 1989).
		Prestrelski, S. J. et al., "Optimization of Lyophilization Conditions for Recombinant Human Interleukin-2 by Dried-State Conformational Analysis Using Fourier-Transform Infrared Spectroscopy," <i>Pharmaceutical Research</i> 12(9):1250-1259 (1995).
		Prestrelski, S. J. et al., "Separation of Freezing- and Drying-Induced Denaturation of Lyophilized Proteins Using Stress-Specific Stabilization," <i>Archives of Biochemistry and Biophysics</i> 303(2):465-473 (June 1993).
	44	"Aerosols, Metered-Dose Inhalers, and Dry Powder Inhalers", <i>Pharmacopeial Previews</i> , 22(6): 3065 (1996).
		Quan. C. <i>Protein Science</i> 4(2):148, Abstract No. 490-T (1995)
		Ramanujam, R. et al., "Ambient-Temperature-Stable Molecular Biology Reagents," <i>Biotechniques</i> 14(3):470-473 (1993).
	45	Ringe, D. et al., "The Glass Transition in Protein Dynamics: What it is, Why it Occurs, and How to Exploit It", <i>Biophys. Chem.</i> 105(2-3):667-680, Abstract only, [on-line] [retrieved 11/19/04] Retrieved from the Internet < URL: <a href="http://www.ncbi.nlm.nih.gov">http://www.ncbi.nlm.nih.gov</a> > (2003).
		Roos, "Phase Transitions of Mixtures of Amorphous Polysaccharides and Sugars," <i>Biotechnology Progress</i> 7(1): 49-53 (1991).

<b>Examiner:</b>	<b>Date Considered</b>

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
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<u>Page 22 of 25</u> <i>(Use Several Sheets if Necessary)</i>		<b>Filing Date:</b> August 19, 2003	<b>Group:</b> 1616
<b>Other Documents</b>			

46	Rosen, Surfactants and Interfacial Phenomena", Second Edition, John Wiley & Sons, New York, pp. 326-329 (1989).
	Roser, et al., "A Sweeter Way To Fresher Food" <i>New Scientist</i> pp. 25-28 (May 15, 1993).
	Roser, B., "Trehalose, A New Approach To Premium Dried Foods," <i>Trends in Food Sci. and Tech.</i> pp. 166-169 (July 1991).
	Roser, B., "Trehalose Drying: A Novel Replacement For Freeze Drying" <i>Biopharm</i> 4:47-53 (1991).
	Sacchetti, et al., "Spray-Drying and Supercritical Fluid Particle Generation Techniques", <i>Inhalation Aerosols: Physical and Biological Basis for Therapy</i> , A.J. Hickey, ed., Marcel Dekkar, New York, Chapter 11, p. 337 (1996).
	Saleki-Gerhardt, A. et al., "Non-Isothermal and Isothermal Crystallization of Sucrose From the Amorphous State," <i>Pharmaceutical Research</i> 11 (8):1166-1173 (1994).
	Saleki-Gerhardt, A. et al., "Hydration and Dehydration of Crystalline and Amorphous Forms of Raffinose," <i>Journal of Pharmaceutical Sciences</i> , 84(3):318-323 (March 1995).
	Sambrook, et al., <u>Molecular Cloning: A Laboratory Manual</u> , 2nd. ed., "CONCENTRATING NUCLEIC ACIDS: Precipitation with Ethanol or Isopropanol", pp. E.10-E.17, Cold Spring Harbor Laboratory Press (1989).
	Sanchez, J. et al., "Recombinant System for Overexpression of Cholera Toxin B Subunit In Vibrio Cholerae as a Basis for Vaccine Development" <i>Proc. Natl. Acad. Sci. USA</i> 86:481-485 (1989).
	Sarkar and Moore, "Immunization of Mice Against Murine Mammary Tumor Virus Infection and Mammary Tumor Development," <i>Cancer Research</i> 38:1468-1472 (1978).
47	Satoh, Koichi, "Determination of Binding Constants of Ca <sup>2+</sup> , Na <sup>+</sup> , and Cl <sup>-</sup> Ions to Liposomal Membranes of Dipalmitoylphosphatidylcholine at Gel Phase by Particle Electrophoresis", <i>Biochem. Biophys. Acta</i> 1239:239-248 (1995).
	Schamblin and Zografi, "Enthalpy Relaxation in Binary Amorphous Mixtures Containing Sucrose", <i>Pharmaceutical Research</i> 15(12): 1828-1834 (December 1998).
	Schebor, C. et al., "Color Formation Due to Non-Enzymatic Browning in Amorphous, Glassy, Anhydrous, Model Systems", <i>Food Chemistry</i> 65:427432 (1999).
	Schram, L. "The Language of Colloid and Interface Science, A Dictionary of Terms", American Chem. Soc., pg 157 (1993).
48	Sciarrà et al., "Aerosols", <i>Remington's Pharmaceutical Sciences</i> , Chap. 93, 17 <sup>th</sup> Ed., Mack Publishing Company, Alfonso R. Gennaro, editor, pp. 1662-1677 (1985).
	Sehatu, T. et al., "Assessment of the Degree of Disorder in Crystalline Solids by Isothermal Microcalorimetry," <i>International Journal of Pharmaceutics</i> 104:135-144 (1994).
53	Sellers, S. P. et al., "Dry Powders of Stable Protein Formulations From Aqueous Solutions Prepared Using Supercritical CO <sub>2</sub> -Assisted Aerosolization", <i>Journal of Pharmaceutical Sciences</i> , 90(6): 785-797 (2001).
	Serajuddin, A. T. M. et al., "Effect of Thermal History on the Glassy State of Indapamide," <i>J. Pharm. Pharmacol.</i> 38:219-220 (1986).

Examiner:	Date Considered

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO/SB/08A (Modified)

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(Use Several Sheets if Necessary)

Applicant:

Weers et al.

Filing Date:

August 19, 2003

Group:

1616

**Other Documents**

		Shalaev, E. Y. et al., "How Does Residual Water Affect The Solid-State Degradation of Drugs in the Amorphous State", <i>Journal of Pharmaceutical Sciences</i> , 85(11): 1137-111 (1996).
		Shalaev, E.Y. et al., "Structural Glass Transitions and Thermophysical Processes in Amorphous Carbohydrates and Their Supersaturated Solutions," <i>J. Chem. Soc. Faraday Trans.</i> 91(10):1511-1517 (1995).
49		Sharma, V. K. et al., "Effect of Vacuum Drying on Protein-Mannitol Interactions: The Physical State of Mannitol and Protein Structure in the Dried State", AAPS PharmSciTech 5(1) Article 10:1-12 [on-line] [retrieved] Retrieved from the Internet <URL: <a href="http://www.aapspharmschitech.org">http://www.aapspharmschitech.org</a> > (2004).
		Singer et al., "Thermotolerance in <i>Saccharomyces Cerevisiae</i> : the Yin and Yang of Trehalose", <i>Tibtech</i> 16:460-468. (1998).
		Skrabanja et al., "Lyophilization of Biotechnology Products" <i>PDA J. Pharm. Sci. Technol.</i> 48(6):311.
		Slade and Levine, "The Glassy State Phenomenon in Food Molecules," <i>The Glassy State in Foods</i> , Blanshard & Lillford, editors: 35-101 (1993).
		Slade and Levine, "Non-Equilibrium Behavior of Small Carbohydrate-Water Systems," <i>Pure and Applied Chemistry</i> , 60(12): 1841-1864 (1988).
		Sokolov et al., "Glassy Dynamics in DNA: Ruled by Water of Hydration" <i>Journal of Chemical Physics</i> 110(14):7053-7057 (1999).
		Sola-Penna, Mauro et al., <i>Stabilization Against Thermal Inactivation Promoted by Sugars on Enzyme Structure and Function: Why is Trehalose More Effective Than Other Sugars?</i> 360(I) ARCHIVES OF BIOCHEMISTRY AND BIOPHYSICS 10-14, Article No. BB9809606, (December 1998).
50		Sonner, C. et al., "Spray-Freeze-Drying for Protein Powder Preparation: Particle Characterization and a Case Study With Trypsinogen Stability", <i>Journal of Pharmaceutical Sciences</i> 91(10):2122-2139 (2002).
51		Spi Polyols™ "What are Polyols? What do Polyols do? What are Polyols' functionality?", [on-line] [retrieved 06/25/04] Retrieved from the Internet <URL: <a href="http://www.spipolyols.com/whatarepolyols.html">http://www.spipolyols.com/whatarepolyols.html</a> > one page (2003).
		Stribling, R. et al., "Aerosol Gene Delivery in Vivo," <i>Proc. Natl. Acad. Sci.</i> 89:11277-11281 (December 1992).
		Strickley, R. G. et al., "Solid-State Stability of Human Insulin II. Effect of Water on Reactive Intermediate Partitioning in Lyophiles from pH 2-5 Solutions: Stabilization Against Covalent Dimer Formation", <i>Journal of Pharmaceutical Sciences</i> 86(6):645-653 (1997).
		Strom, A. R. and Kaasen, I. "Trehalose Metabolism in <i>Escherichia coli</i> : Stress Protection and Stress Regulation of Gene Expression", <i>Molecular Microbiology</i> 8(2):205-210 (1993).
		Stubberud, L. et al., "The Use of Gravimetry For The Study of the Effect of Additives on the Moisture-Induced Recrystallisation of Amorphous State", <i>International Journal of Pharmaceutics</i> 163:145-156 (1998).
		Suknenik et al., "Enhancement of a Chemical Reaction Rate by Proper Orientation of Reacting Molecules in the Solid State", <i>J. Am. Chem. Soc.</i> 97: 5290-5291 (September 1975).

**Examiner:****Date Considered**

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
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		<b>Filing Date:</b> August 19, 2003	<b>Group:</b> 1616
<b>Other Documents</b>			

	Sussich, F. et al., "Reversible Dehydration of Trehalose and Anhydrobiosis: From Solution State to an Exotic Crystal?", <i>Carbohydrate Research</i> 334:165-176 (2001).
	Takahashi et al., "Induction of CD8+ cytotoxic T cells by immunization with purified HIV-1 envelope protein in ISCOMs", <i>Nature</i> 344:873-875 (April 1990).
	Tarara, T. et al., "Characterization of Suspension-Based Metered Dose Inhaler Formulations Composed of Spray-Dried Budesonide Microcrystals Dispersed in HFA," <i>J. Pharm Res.</i> Vol. 21, No. 9, pp. 1607-1614 Sept. 2004
	Tarelli, E. et al., "Additives to Biological Substances. 144. The Moisture Content and Moisture Uptake of Commonly Used Carrier Agents Undergoing Processing Conditions Similar to Those Used in the Preparation of International Biological Standards," <i>Journal of Biological Standardization</i> 15:331-340 (1987).
52	Thatcher, E., "Quantitation of Virus" [on-line] [retrieved 1/10/1/04] Retrieved from the Internet <URL: <a href="http://www.sonoma.edu/users/t/thatcher/biol383/lab.htm">http://www.sonoma.edu/users/t/thatcher/biol383/lab.htm</a> > 4 pages, (last updated Jan. 5, 2002).
	Timko et al., "Thermal Analysis Studies of Glass Dispersion Systems", <i>Drug Devel. Ind. Pharm.</i> 10:425-451 (1984).
	Timsina, T. et al., "Drug Delivery to the Respiratory Tract Using Dry Powder Inhalers," <i>International Journal of Pharmaceutics</i> 101:1-13 (1994).
53	To et al., "Collapse. a Structural Transition in Freeze Dried Carbohydrates", <i>J. Fd. Technol.</i> 13: 567-581 (1978).
	Toyama, A. (ed) <u>Handbook of Natural Product for food processing</u> , 9th Edition, Osaka, Japan, Shokuhin to Kagaku Sha, pages 384 and 495 (ISBN4-87994-048-8), (1986).
	Tsourouflis, S. et al., "Loss of Structure in Freeze-Dried Carbohydrates Solutions: Effect of Temperature, Moisture Content and Composition," <i>J. Sci. Fd. Agric.</i> 27:509-519 (1976).
54	Ulrich, "Biophysical Aspects of Using Liposomes as Delivery Vehicles", <i>Bioscience Reports</i> 22(2):129-150 (2002).
	Underwood et al., "A Novel Technique for the Administration of Bronchodilator Drugs Formulated as Dry Powders to the Anaesthetized Guinea Pig", <i>J. of Pharmacological Methods</i> , Vol. 26, pp. 203-210, 1991.
	Uritani, M. et al., "Protective Effect of Disaccharides on Restriction Endonucleases During Drying Under Vacuum." <i>J. Biochem.</i> 117:774-779 (1995).
	Vain et al., "Development of the particle inflow gun", <i>Plant Cell, Tissue and Organ Culture</i> 33:237-246 (1993).
	Vavelyuk, O.L. et al., "Thermostability of DNA and Its Association with Vitrification", <i>Tsitologiya</i> 41(11):958-965 (1999).
	Vidgrén, M. T. et al., "Comparison of Physical and Inhalation Properties of Spray-Dried and Mechanically Micronized Disodium Cromoglycate," <i>International Journal of Pharmaceutics</i> 35:139-144 (1987).
	Vromans, H. et al., "Studies on Tableting Properties of Lactose. VII. The Effect of Variations in Primary Particle Size and Percentage of Amorphous Lactose in Spray-Dried Lactose Products," <i>International Journal of Pharmaceutics</i> 35:29-36 (1987).
	Wang, et al. eds. <u>Stability and characterization of protein and peptide drugs</u> , Table of Contents, 6 pages (1993).

Examiner:	Date Considered

Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>Form PTO/SB/08A (Modified)</b>		<b>Atty. Docket No.:</b> 0056.11	<b>Application No.:</b> 10/644,256
<b>Information Disclosure Statement By Applicant</b>		<b>Applicant:</b> Weers et al.	
<u>Page 25 of 25</u> <i>(Use Several Sheets if Necessary)</i>		<b>Filing Date:</b> August 19, 2003	<b>Group:</b> 1616
<b>Other Documents</b>			

		Welsh, D. T., "The Role of Compatible Solutes In the Adaptation and Survival of <i>Escherichia coli</i> ," Ph.D. Thesis Submitted to Department of Biological Sciences, University of Dundee. pp. 1-262 . (August 1992).
		Whittier, E., "Lactose and its Utilization: A Review," <i>J. Dairy Sci.</i> 27(7)505-537 (July 1994).
		William and Leopold, "The Glassy State in Corn Embryos" <i>Plant Physiology</i> 89:977-981 (1979).
		Williams et al., "The Temperature Dependence of Relaxation Mechanisms in Amorphous Polymers and Other Glass Forming Liquids", <i>The Journal of the American Chemical Society</i> 77: 3701-3707 (1955).
		Wolff, J. A. et al., "Grafting Fibroblasts Genetically Modified to Produce L-Dopa in a Rat Model of Parkinson Disease," <i>Proc. Natl. Acad. Sci.</i> 86:9011-9014 (November 1989).
		Xi, Y. G. et al., "Amphotericin B Treatment Dissociates in Vivo Replication of the Scrapie Agent From PrP Accumulation", <i>Nature</i> 356:598-601 (April 1992).
		York, "Powdered Raw Materials: Characterizing Batch Uniformity," <i>Respiratory Drug Delivery IV, Programs and Proceedings</i> , edited by Byron, Dalby and Farr: 83-91 (1994).
55		Yoshida, H. et al., "Absorption of Insulin Delivered to Rabbit Trachea Using Aerosol Dosage Form," <i>Journal of Pharmaceutical Sciences</i> 68(5): 670-671 (May 1979).
56		Yoshinari, T. et al., "Moisture Induced Polymorphic Transition of Mannitol and its Morphological Transformation", <i>International Journal of Pharmaceutics</i> , 247:69-77 (2002).
		Yoshioka, M. et al., "Crystallisation of Indomethacin From the Amorphous State Below and Above Its Glass Transition Membrane," <i>Journal of Pharmaceutical Sciences</i> 83(12):1700-1705 (December 1994).
		Zubay, G. BIOCHEMISTRY, SECOND EDITION, pages 39 & 169, Table 5-6 Major Steroid Hormones (1988).
		Zubay, G. BIOCHEMISTRY, SECOND EDITION, pages 210-232 "Structural Properties of DNA" (1988).
57		Nektar U.S. Patent Application No. 08/044,358, "Compositions and Methods For Nucleic Acid Delivery To The Lung" filed by Patton et al. on April 7, 1993, assigned to Inhale Therapeutic Systems.
58		Nektar U.S. Patent Application No. 08/422,563, filed April 14, 1995, Paper No. 17, Office communication mailed April 3, 1998 (Patent No. 5,994,314).

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